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PI - Signature Date
Edwin G. Wilkins, M.D. 7/18/96

**MICHIGAN BREAST RECONSTRUCTION OUTCOME STUDY
YEAR TWO REPORT, JULY 17, 1996**

TABLE OF CONTENTS

ABSTRACT	2
INTRODUCTION	3
Background and Relevance.....	3
Objectives.....	4
Purpose/ Hypotheses.....	4
Summary of Methods;.....	4
BODY (PROJECT STATUS).....	6
A. Continue New Patient Recruitment.....	6
B. Administer pre-op functional tests and questionnaires to new study patient, initiate patient logs of outpatient care.....	8
C. Administer postoperative functional tests questionnaires to study patients enrolled in months 1-12.....	8
D. Begin acquisition of clinical data from participating hospitals and surgeons.....	8
E. Resolve any problems with acquisition of cost data. Obtain cost data on patients enrolled in months 7-18, in addition to cost data on post-operative services provided to patients enrolled in months 1-6. Validate outpatient log data with outpatient computer-based data from UM Hospitals.....	8
CONCLUSIONS	9
PRESENTATIONS	11
ATTACHMENT A-PRE-SURGERY AND POST-SURGERY EVALUATION FORMS	
ATTACHMENT B-MBROS HOSPITAL CHART REVIEW FORM	
ATTACHMENT C-MBROS COMPLICATIONS CHECK LIST	

ABSTRACT

The objective of the Michigan Breast Reconstruction Outcome Study (MBROS) is to compare the long-term outcomes of two common techniques of post-mastectomy breast reconstruction: tissue expansion/breast implants and transverse rectus abdominis musculocutaneous (TRAM) flaps. The four year prospective study seeks to adapt existing instruments and formulate new methodologies to assess outcomes in five categories: complication rates, aesthetic results, functional results, psychosocial status and costs. Measurements of outcome variables are obtained prior to reconstruction and at annual intervals starting one year after the procedure. Instruments used include questionnaires, physical testing, evaluation of digitized photographs, and analysis of billing and hospital record data.

Since MBROS was initiated in September, 1994, 260 patients have been recruited. The project has been expanded to include 22 collaborating plastic surgeons and 13 medical centers in Michigan, Louisiana, Pennsylvania and Ontario, Canada. Active study participants include women undergoing expander/implant (23%), pedicle TRAM flap (43%), free TRAM (30%), and Lat Dorsi (4%) reconstructions. Sixty-three patients have satisfied the second year study requirements by completing a post-surgery evaluation form and a second year physical assessment. At this time, we anticipate that a total of 400 patients will ultimately be enrolled in the project.

INTRODUCTION

Background and Relevance

Each year in the United States, breast cancer strikes over 180,000 women. Although most of these patients are candidates for breast-conserving therapy (usually in the form of lumpectomy and postoperative radiation), many still undergo mastectomy. Loss of one or both breasts constitutes a major psychosocial stress for women already struggling to cope with a life-threatening illness. The disruptions in body image, interpersonal relationships, and other aspects of psychosocial functioning which result from mastectomy often have a significant negative effect on the recovering cancer patient's quality of life.

Previous research has clearly demonstrated the benefits of breast reconstruction for women undergoing mastectomy. Whether performed at the time of mastectomy or as a later secondary procedure, breast reconstruction may prevent or reverse many of the emotional and psychological disturbances seen in women undergoing mastectomy. Common sequelae such as impaired sense of well-being, compromised femininity, decreased feelings of sexual desirability can be reversed by the restoration of form and function.

Based on recent figures, there is a growing public acceptance of and demand for breast reconstruction. The American Society for Plastic and Reconstructive Surgeons estimates that 43,000 of these procedures were performed by its members during 1990. In 1990 (the most recent year for which data is available), expander-implant techniques constituted the majority of procedures for breast reconstruction. However, with the recent controversy over the safety and effectiveness of silicone gel breast implants, natural (autogenous) tissue techniques, most notably the transverse rectus abdominis musculocutaneous (TRAM) flap, have become increasingly common. Although they avoid the potential complications of prosthetic implants, TRAM flaps are more complex and expensive procedures. Given the growing prevalence of breast reconstruction in the United States, expander-implant and TRAM procedures are responsible for an annual outlay of health care dollars in the hundreds of millions.

Although considerable resources are currently being spent on breast reconstruction, relatively little information is available on comprehensive long-term outcomes of this treatment modality. There is a critical need for statistically credible research which reflects not just the technical feasibility and aesthetics of breast reconstruction, but which also shows the functional, psychological, and social benefits of such procedures. Finally, these demonstrated benefits of reconstruction must be assessed in relation to the costs of such operations. In essence, we must demonstrate the *value* of breast reconstruction.

Objectives

The objective of the Michigan Breast Reconstruction Outcome Study (MBROS) is to compare the long-term outcomes of the two most common techniques of post-mastectomy breast reconstruction: tissue expansion/breast implants and transverse rectus abdominis musculocutaneous (TRAM) flaps. A four year prospective study, the project is adapting existing instruments and formulating new methodologies to assess outcomes in five categories: complication rates, aesthetic results, functional results, psychosocial status and costs. Study results will provide much needed information to patients, providers, and payers for determining the procedure of choice. In addition, the research will establish standardized methods for evaluation of breast reconstruction results in future studies. Finally, initial data assembled by this research can also be used for long-term analysis of breast reconstruction outcomes.

Purpose/ Hypotheses

The purpose of the proposed research is two-fold: (I.) to develop a standard set of instruments for the evaluation of outcomes from breast reconstruction; and (II.) to use these instruments to compare outcomes for patients undergoing expander/implant reconstruction and those receiving TRAM reconstruction.

I. To achieve the first objective, multiple hypotheses will be tested:

- (1) Less costly clinical evaluations of functional outcomes have predictive validity (i.e., correlate highly with measures obtained from more costly isokinetic muscle testing).
- (2) Clinical evaluations of functional outcomes are reliable.
- (3) Less costly subjective assessments of both aesthetic and functional outcomes have predictive validity (i.e., correlate highly with more costly, objective measures).
- (4) Condition-specific, subjective assessments of functional and psychosocial outcomes have greater predictive validity than generic, subjective assessments.
- (5) Subjective assessments of aesthetic, functional, and psychosocial outcomes are reliable.

The results from testing the above hypotheses should identify the set of instruments which provide the most valid and reliable data at the lowest possible cost.

II. To achieve the second objective, multiple outcome measures of expander/implant and TRAM reconstructions will be assessed. The following null hypothesis will be tested for comparing outcomes from the two reconstruction procedures:

- (6) For expander/implant and TRAM procedures, there will be no differences in the five measured outcomes: (a) complication rates; (b) aesthetic results; (c) functional results; (d) psychosocial status; and (e) overall costs

Summary of Methods

Using patients recruited from the practices of 22 plastic surgeons and 13 medical centers in Michigan, New Orleans, Pennsylvania and Toronto, Ontario, Canada, the Michigan Breast Reconstruction Outcome Study (MBROS) is a prospective study comparing the outcomes of expander/implant and TRAM reconstructions. As noted above, outcomes measured include complications, aesthetic results, functional results, psychosocial status, and costs. Patients are followed for two years; function and psychosocial status are assessed preoperatively, while all five outcome parameters are measured postoperatively at one year intervals.

The proposed research is a non-equivalent treatment group, multi-factor, full factorial design, with pre-test and post-test data collected prospectively. The two treatment groups are (1) patients undergoing breast reconstruction using tissue expansion/implants, and (2) patients undergoing reconstruction using TRAM flaps.

The multi-factor aspect of the proposed research design, as well as the use of pre-test and post-test measures for several of the outcomes of interest, are intended to control for the

differences in the patient populations between the two procedure groups. The factors to be included in the design, plus the number of levels of each, are described below:

- (1) Procedure type; two levels: (a) tissue expanders/implants and (b) TRAM flaps
- (2) Timing of procedure; two levels: (a) *immediate* (reconstruction at the time of mastectomy) and (b) *delayed* (reconstruction months or years following mastectomy)
- (3) Scope of procedure; two levels: (a) unilateral and (b) bilateral.
- (4) Surgeon; 22 levels (one for each surgeon who has agreed to participate).

The pre-treatment measurements of outcome variables are obtained prior to surgery. Post-treatment measurements will be collected at a minimum of two different time points after surgery. This approach will identify the cumulative effect of some measures (e.g., complications and costs) and will help determine the earliest time point at which the other outcomes stabilize (e.g., functional and psychosocial status). The post-treatment data collection periods will be at one year following surgery and at annual intervals thereafter. Two of the outcome measures, complication rates and costs, will be measured post-treatment only, as they are characteristics of the treatment itself, and therefore, have no pre-treatment measures.

As noted above, MBROS will study five outcomes of breast reconstruction: complications, aesthetic results, functional results, psychosocial status, and costs. A variety of methods are being used to measure these parameters: in some cases, existing instruments are being employed in their original form, while in other instances, existing methodology is being modified to better assess the outcomes of interest. New techniques are also being tested for several of the five outcome parameters.

Postoperative complications will be assessed with hospital chart and office record reviews at the conclusion of each patient's two year study participation. *Aesthetic results* will also be evaluated on the second anniversary following reconstruction using three different approaches: (1) computer analysis of digitized postoperative photographs; (2) physician ratings of post-operative photographs; and (3) patients' assessments of their own aesthetic results. Back, abdominal wall, and shoulder *function* is being examined preoperatively and at one and two year intervals after surgery with objective assessments (Cybex isokinetic testing). The effects of reconstruction on physical functioning are also being studied with activities of daily living (ADL) items on the study questionnaire administered at the same time intervals. To examine *psychosocial outcomes*, the preoperative and postoperative study questionnaires contain condition-specific questions as well as a battery of existing instruments including the SF-36, Basic Symptom Inventory (BSI), Modified Somatic Perception Questionnaire (MSPQ), and the Functional Assessment of Cancer Therapy (FACT). Finally, *costs of reconstruction* will be assessed at the conclusion of each patient's two year participation using hospital billing data in Relative Value Units (RVUs).

BODY

Project Status

MBROS was funded by the U.S. Army in July of 1994 for a four year period. After the hiring and training of project personnel, the study was initiated in late September, 1994. As described in the Statement of Work (SOW) included in the proposal, the goals for the second year of the project are listed below. Progress made during the past year towards completion of each milestone is also detailed.

MBROS Statement of Work (Months 13-24)

A. Continue New Patient Recruitment

One hundred and sixty patients were enrolled during the second year of the project. Although recruitment rates have improved significantly over the previous year, additional subjects are still needed to reach the goals set by our sample size calculations. To achieve these goals, several additional steps have been taken in the last twelve months. To encourage and facilitate further physician referral of patients, we are now reimbursing collaborating physicians \$30.00 for each patient recruited. These funds are intended to help defray the costs of office personnel time, long distance telephone calls, etc., involved in referring women for the project. In addition, our study coordinator has traveled to the participating sites and met with the office staffs of participating physicians. The visits have helped to familiarize office personnel with MBROS recruitment procedures and have provided an opportunity for us to encourage more regular participation. We have also increased telephone and mail communication with the referring physician offices in an effort to remind them to refer patients to us for enrollment in the study. We believe these efforts have resulted in the increased referrals we have seen in the months of May, June and July of 1996.

Because we have not yet reached our goal of 400 active patients, we propose to continue patient recruitment into the third year of the study. For the women who volunteer during the third year of this four year project, we will be able to complete only the one year post-operative assessments prior to the project's conclusion. As indicated above, the study protocol includes both one and two year post-op evaluations. Because most of the outcomes of interest appear to stabilize at one year following treatment, this adjustment should not compromise the statistical integrity of the study. However, with two year followup available on approximately 300 of the 400 total study subjects, we will be able to identify any outcome parameters which fail to stabilize at one year post-treatment.

Patient Enrollment By Month: Year Two MBROS

JULY, 1995 (last 2 Weeks)	11
AUGUST, 1995	13
SEPTEMBER, 1995	9
OCTOBER, 1995	16
NOVEMBER, 1995	14
DECEMBER, 1995	6
JANUARY, 1996	9
FEBRUARY, 1996	15
MARCH, 1996	13
APRIL, 1996	9
MAY, 1996	13
JUNE, 1996	22
JULY (first 2 weeks)	11
TOTAL	160

Patient enrollment by physician for the time period July 15, 1995 to July 17, 1996 is shown below: MICHIGAN BREAST RECONSTRUCTION OUTCOME STUDY, YEAR 2

PHYSICIAN	No. of Patients	No. Withdrawn	No. of TRAMS	No. of Implants	No. of Lat Dorsi	No. Immed.	No. Delayed	HOSPITAL
Wilkins, Edwin	21	0	14	5	2	8	13	Univ of Mich.
Shaheen, Ken	15	3	2	10	0	11	1	Beaumont
Izenberg, Paul	15	0	11	4	0	15	0	St. Josephs
Houin, Herman	7	0	7	0	0	5	2	Henry Ford
Beil, Richard	12	2	6	3	1	10	0	St. Josephs
Hammond, Dennis	12	2	6	2	2	10	0	St. Mary's
Schenden, Michael	0	0	0	0	0	0	0	Beaumont
Bengston, Bradley	5	1	4	0	0	4	0	Holland Comm
Drever, Michael	26	2	20	1	3	23	1	Toronto General
Darian, Vigan	6	0	3	3	0	5	1	Henry Ford
Nelligan, Peter	1	0	1	0	0	0	1	Toronto General
Smith, David	1	0	1	0	0	1	0	Univ of Mich.
Mizgala, Cynthia	8	0	4	2	2	4	4	Ochsner Med. Ctr.
Sherbert, Dan	7	2	5	0	0	3	2	Sinai Hosp.
Ringler, Steve	1	0	1	0	0	0	1	Holland Comm
Semple, John	18	2	15	1	0	9	7	Women's College
Ganos, Doreen	2	0	2	0	0	1	1	Henry Ford
Brundage, Scott	1	0	1	0	0	0	1	Butterworth
Ladin, Daniel	1	0	1	0	0	1	0	Henry Ford
Banducci, Dennis	1	1	0	0	0	0	0	Hershey Med. Ctr.
Colony, Lee	0	0	0	0	0	0	0	Mich. State
Kuzon, William	0	0	0	0	0	0	0	Univ of Mich
TOTAL	160	15	104	31	10	110	35	

Patient Withdrawals

During the second year of the study 20 patients (5 first year patients and 15 second year patients) have been withdrawn from the study due to :

- (1) Not completing either the pre-operative questionnaire or functional assessment prior to surgery (8 patients or 40%);
- (2) Inability to physically complete the functional assessment because of co-morbid problems (4 patients or 20%);
- (3) Patient changed her mind about wanting to participate (2 patients or 10%);
- (4) Patient canceled surgery (2 patients or 10%)
- (5) Patient's surgical treatment option changed during the study due to complications (i.e. began as expander/implant, changed to TRAM reconstruction or the reverse) (4 patients or 20%)

B. Administer preoperative functional tests and questionnaires to new study patients.

Pre-operative functional tests and questionnaires have been administered to 230 active patients. Patient compliance has been excellent with 94.5% of new study volunteers successfully completing both the preoperative questionnaire and Cybex assessments. In cases where the participating physician enrolls a patient but neglects to give the patient her questionnaire, the necessary materials are mailed to the enrollee to ensure timely completion. Scheduling for Cybex functional exams is coordinated through the UM Outcomes Office to ensure that study patients receive their assessments prior to reconstruction.

A copy of the preoperative patient questionnaire is included in Attachment A.

C. Administer post-operative functional tests and questionnaires to study patients enrolled during months 1-12.

Sixty-three patients have completed the post-operative functional test and questionnaire, thus having fulfilled the second year study requirements. Four more have been scheduled for their second physical assessment and sent their post-operative questionnaires. Compliance in the post-treatment population has continued to be outstanding, with only one patient not completing the post-operative questionnaire and Cybex functional exams. Eleven patients have had their post-operative functional assessments delayed due to secondary surgical procedures such as expander/implant exchange or nipple reconstruction, or due to surgical procedures to treat complications of the original reconstructive procedure.

A copy of the postoperative patient questionnaire is included in Attachment A.

D. Begin acquisition of clinical data from participating hospitals and surgeons.

In preparation for collection of clinical data from hospital charts and physician records, a chart abstraction instrument has been developed. (See Attachment B) In addition, corresponding data fields have been created within the Foxpro database for entry of this information. A part-time undergraduate work-study student is being trained in chart reviews and data entry. At the conclusion of each patient's two-year study participation, the work-study student will abstract the necessary data from the medical record. In collaborating physicians' offices, a complication check-list has been attached to each study patient chart. (See Attachment C) These check-lists will be returned to the UM Outcomes Office following the end of the two year period and will serve as an additional mechanism for collecting complication data and for verifying hospital record information on adverse post-operative events.

E. Resolve any problems with acquisition of cost data. Obtain cost data on patients enrolled in months 7-18, in addition to cost data on post-operative services provided to patients enrolled in months 1-6. Validate outpatient log data with outpatient computer-based data from UM hospitals.

The comparison of costs between the TRAM and implant methods of reconstruction is one of the five categories in which patient outcomes will be studied. The total cost of treatment for each study patient will consist of all professional and hospital costs associated with the patient's hospitalization for the reconstruction, plus the costs of any subsequent care received (inpatient or outpatient) that is related to the reconstruction.

Because of the lack of standardization across hospitals in the relationship of costs to charges, the measurement of costs for this research is carried out using Relative Value Units (RVUs). RVUs have been determined for each of the University of Michigan Hospital's fee codes

by multiplying the ratio of an individual fee codes charge to a department's total charges by the department's total direct costs: (indirect costs are excluded from the calculations).

Hospital charge/billing information is typically incomplete for a period of three to six months following the rendering of patient services. Analysis of patient costs data has begun for UM patients utilizing the RVU system previously discussed. Components of total financial costs are:

- **Category A:** Hospital costs, i.e., operating room, associated costs, and room costs (inpatient and outpatient)
- **Category B:** Professional fees, i.e., reconstructive surgeon and anesthesiology costs (inpatient and outpatient)
- **Category C:** Complications (inpatient and outpatient)

Billing and RVU data are obtained on all University of Michigan patients as soon as they become available. In addition, we have received patient billing data on all patients from St. Joseph's Mercy Hospital enrolled before March, 1996. We have also requested billing data from two other Michigan Hospitals with a high number of enrolled patients. We will continue requesting billing data from the participating hospitals as necessary.

Michigan RVUs are available for all hospital services, but not for professional services. Therefore, work has been proceeding on identifying an appropriate conversion factor for translating professional charges into RVUs. In addition, we are working on mapping billing data from St. Joseph- Mercy Hospital's patients to University of Michigan RVUs; we will continue this process for the other participating institutions as we receive their billing data.

CONCLUSION

In the next twelve months, work within MBROS will concentrate on several areas:

- (1) Sustain an adequate rate of new study participant recruitment through efforts outlined in Section A above.
- (2) Continue administration of postoperative functional tests and questionnaires.
- (3) Initiate collection of clinical data from participating hospitals and surgeons. Collect data on outpatient services from patients.
- (4) Continue to refine and test outcomes instruments.
- (5) Begin preliminary analysis of functional and psychosocial data. Refine methods for analysis of this data.
- (6) Begin analysis of financial data. Refine methodology for financial analysis.
- (7) Conduct aesthetic evaluations (surgeon evaluator ratings, patient ratings and anthropometric assessments) of patients enrolled in months 1-12.

As noted earlier, the objectives of MBROS are two-fold: (I.) to develop a standard set of instruments for the evaluation of outcomes from breast reconstruction; and (II.) to use these instruments to compare outcomes for patients undergoing expander/implant reconstruction and those receiving TRAM reconstruction. Significant progress towards achieving the project goals has been accomplished during the second year. Continuing present efforts to expand the study's patient population and maintaining adequate follow-up present the greatest challenges for the coming twelve months.

By accomplishing its objectives, MBROS will yield several important benefits. Instruments developed, refined and tested during the project can be used by other investigators for the ongoing monitoring of the quality of breast reconstruction. MBROS will yield information for use by patients and health care providers in selecting breast reconstruction procedures. Finally, completion of the project will produce a multicenter database for ongoing studies on the long-term outcomes of breast reconstruction.

PRESENTATIONS

Wilkins EG, "Update on the Michigan Breast Reconstruction Outcome Study": Breast Surgery in the Nineties. Symposium Sponsored by the Plastic Surgery Educational Foundation. January, 1995, Atlanta, Georgia

Wilkins EG, "Outcomes Research in Breast Surgery": Breast Surgery in the Nineties. Symposium Sponsored by the Plastic Surgery Educational Foundation. January, 1995, Atlanta, Georgia

PUBLICATIONS

Lowery J.C., Wilkins E.G. and Kuzon W.M. Analysis of Instruments for Assessment of Aesthetic Outcomes in Breast Reconstruction. *Annals of Plastic Surgery*, 36:601-607, 1996.

Wilkins, E.G., Lowery, J.C., Smith, Jr., D.J. Outcomes Research - A Primer for Plastic Surgeons. (Accepted by *Annals of Plastic Surgery*, 1996).

Segar M.E., Katch V.L., Roth R.S., Garcia A.W., Portner T.I., Glickman S.G., Haslanger S., and Wilkins E.G.. Aerobic Exercise Reduces Depressive and Anxiety Symptoms, but not Self-esteem Among Breast Cancer Survivors. (Submitted to *Oncology Nursing Forum*, February, 1996).

ATTACHMENT A

PRE-SURGERY AND POST-SURGERY EVALUATION FORMS

Post-Surgery Evaluation
Michigan Breast Reconstruction Outcome Study
University of Michigan, Ann Arbor

(For office use only)
REGISTRATION # _____

I. Personal Information

Today's Date: _____

Your Name: _____

Date of Birth: _____ SS#: _____

Address: _____

City, State, Zip: _____

Telephone: (home) _____ - _____ - _____ (work) _____ - _____ - _____

Contact person or relative who does not live with you:

Name _____

Telephone: (home) _____ - _____ - _____

Satisfaction with Surgery

(Circle One Number on Each Line)	Definitely <u>True</u>	Mostly <u>True</u>	Not <u>Sure</u>	Mostly <u>False</u>	Definitely <u>False</u>
1. Knowing what I know today, I would definitely choose to have breast reconstruction .	1	2	3	4	5
2. Knowing what I know today, I would definitely choose to have the <u>type</u> of reconstruction I had.	1	2	3	4	5
3. The size and shape of my breasts are the same.	1	2	3	4	5
4. My reconstructed breast(s) feel soft to the touch.	1	2	3	4	5
5. Overall, I am satisfied with my reconstruction.	1	2	3	4	5
6. I would recommend the type of reconstructive procedure that I had to a friend.	1	2	3	4	5
7. I felt that I received sufficient information about my reconstruction options to make an informed choice of either the TRAM or Implant procedure.	1	2	3	4	5

General Health Survey

1. In general, would you say your health is: (Circle One Number)

Excellent	1
Very Good	2
Good	3
Fair	4
Poor	5

2. **Compared to one year ago**, how would you rate your health in general **now**?

(Circle One Number)

Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

In one year from now, how do you think your health will be?

(Circle One Number)

Much better than today	1
Somewhat better than today	2
About the same as today	3
Somewhat worse than today	4
Much worse than today	5

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(Circle One Number on Each Line)	Yes Limited a Lot	Yes Limited a Little	Not Limited at All
3. Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing several flights of stairs	1	2	3
7. Climbing one flight of stairs	1	2	3
8. Bending, kneeling or stooping	1	2	3
9. Walking more than one mile	1	2	3
10. Walking several blocks	1	2	3
11. Walking one block	1	2	3
12. Bathing or dressing yourself	1	2	3
13. Bending over to brush your teeth	1	2	3
14. Sitting up in bed when you awake in the morning	1	2	3
15. Doing the dishes	1	2	3
16. Arising from a chair	1	2	3
17. Grasping for something, like reaching for a glass from the cupboard	1	2	3

During the **past four weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(Circle One Number on Each Line)	Yes	No
18. Cut down the amount of time you spent on work or other activities	1	2
19. Accomplished less than you would like	1	2
20. Were limited in the kind of work or other activities	1	2
21. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

During the **past four weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

- | (Circle One Number on Each Line) | Yes | No |
|--|-----|----|
| 22. Cut down the amount of time you spent on work or other activities | 1 | 2 |
| 23. Accomplished less than you would like | 1 | 2 |
| 24. Didn't do work or other activities as carefully as usual | 1 | 2 |

25. During the **past four weeks**, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups?

- (Circle One Number)
- | | |
|-------------|---|
| Not at all | 1 |
| Slightly | 2 |
| Moderately | 3 |
| Quite a bit | 4 |
| Extremely | 5 |

26. How much **bodily** pain have you had during the **past four weeks**?

- (Circle One Number)
- | | |
|-------------|---|
| None | 1 |
| Very mild | 2 |
| Mild | 3 |
| Moderate | 4 |
| Severe | 5 |
| Very severe | 6 |

27. During the **past four weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework?)

- (Circle One Number)
- | | |
|--------------|---|
| Not at all | 1 |
| A little bit | 2 |
| Moderately | 3 |
| Quite a bit | 4 |
| Extremely | 5 |

For each of the following statements, please circle the one answer that best describes how true each statement is for you.

- | (Circle One Number on Each Line) | Definitely True | Mostly True | Not Sure | Mostly False | Definitely False |
|--|-----------------|-------------|----------|--------------|------------------|
| 28. My breasts are without pain. | 1 | 2 | 3 | 4 | 5 |
| 29. My abdomen is sore and painful. | 1 | 2 | 3 | 4 | 5 |
| 30. I am frequently troubled by headaches. | 1 | 2 | 3 | 4 | 5 |
| 31. My abdomen feels tight. | 1 | 2 | 3 | 4 | 5 |
| 32. I have back pain. | 1 | 2 | 3 | 4 | 5 |

These questions are about how you feel and how things have been with you **during the past four weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past four weeks** . . .

(Circle One Number on Each Line)	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
33. Did you feel full of pep?	1	2	3	4	5	6
34. Have you been a very nervous person?	1	2	3	4	5	6
35. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
36. Have you felt calm and peaceful?	1	2	3	4	5	6
37. Did you have a lot of energy?	1	2	3	4	5	6
38. Have you felt downhearted and blue?	1	2	3	4	5	6
39. Did you feel worn out?	1	2	3	4	5	6
40. Have you been a happy person?	1	2	3	4	5	6
41. Did you feel tired?	1	2	3	4	5	6

42. During the **past four weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

(Circle One Number)

All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

How TRUE or FALSE is each of the following statements for you?

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
43. I seem to get sick a little easier than other people.	1	2	3	4	5
44. I am as healthy as anybody I know.	1	2	3	4	5
45. I expect my health to get worse.	1	2	3	4	5
46. My health is excellent.	1	2	3	4	5

Personal Beliefs

The following items describe feelings that one may have about their appearance and attractiveness. Please circle the number that best describes how true each statement is for you.

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
47. I believe that physical attractiveness is important in day-to-day social interaction.	1	2	3	4	5
48. I believe that physical attractiveness is important in acquiring a mate (e.g., spouse, significant other).	1	2	3	4	5
49. I believe that physical attractiveness is important in attracting a sexual partner.	1	2	3	4	5
50. My breasts have always been an important part of my sexuality.	1	2	3	4	5
51. Physical and sexual attractiveness have always been very important to me.	1	2	3	4	5

The following items relate specifically to your feelings about the appearance of your breasts. Please circle the answer that best describes the way you now feel.

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
1. I feel whole.	1	2	3	4	5
2. I like the way my blouses/sweaters fit.	1	2	3	4	5
3. I like the way I look in a bathing suit.	1	2	3	4	5
4. My bra fits comfortably.	1	2	3	4	5
5. I feel attractive.	1	2	3	4	5
6. I think of my cancer when I look at my breasts.	1	2	3	4	5
7. I like the appearance of my breasts.	1	2	3	4	5
8. My significant other likes the appearance of my breasts.	1	2	3	4	5
9. I feel self-conscious during sexual activity because of the appearance of my breasts.	1	2	3	4	5

Health Complaints

1. The following items describe bodily symptoms that most of us have experienced at one time or another. Please circle the number that corresponds best with the way you have felt during the PAST WEEK. Please answer all questions. Do not think too long before answering.

	Not at all	A little/ slightly	A great deal/ quite a bit	Extremely could not have been worse
Heart rate increase	1	2	3	4
Feeling hot all over	1	2	3	4
Sweating all over	1	2	3	4
Sweating in a particular part of the body	1	2	3	4
Pulse in neck	1	2	3	4
Pounding in head	1	2	3	4
Dizziness	1	2	3	4
Blurring of vision	1	2	3	4
Feeling faint	1	2	3	4
Everything appearing unreal	1	2	3	4
Nausea	1	2	3	4
Butterflies in stomach	1	2	3	4
Pain or ache in stomach	1	2	3	4
Stomach churning	1	2	3	4
Desire to pass water	1	2	3	4
Mouth becoming dry	1	2	3	4
Difficulty swallowing	1	2	3	4
Muscles in neck aching	1	2	3	4
Legs feeling weak	1	2	3	4
Muscles twitching or jumping	1	2	3	4
Tense feeling across forehead	1	2	3	4
Tense feeling in jaw muscles	1	2	3	4

2. Here is a list of health problems that usually last for some time. Do you have any of the following problems? (Check all that apply)

Yes

No

<input type="checkbox"/>	<input type="checkbox"/>	Asthma
<input type="checkbox"/>	<input type="checkbox"/>	Chronic bronchitis or emphysema
<input type="checkbox"/>	<input type="checkbox"/>	Arthritis or rheumatism
<input type="checkbox"/>	<input type="checkbox"/>	High blood pressure
<input type="checkbox"/>	<input type="checkbox"/>	Angina
<input type="checkbox"/>	<input type="checkbox"/>	Congestive heart failure
<input type="checkbox"/>	<input type="checkbox"/>	History of stroke
<input type="checkbox"/>	<input type="checkbox"/>	Cancer (other than breast or skin cancer: specify type _____)
<input type="checkbox"/>	<input type="checkbox"/>	Diabetes
<input type="checkbox"/>	<input type="checkbox"/>	Chronic back trouble
<input type="checkbox"/>	<input type="checkbox"/>	Lupus
<input type="checkbox"/>	<input type="checkbox"/>	Scleroderma
<input type="checkbox"/>	<input type="checkbox"/>	Other _____

3. Approximately how many times during the PAST SIX MONTHS have you had to visit a doctor because of physical symptoms or follow-up care **related** to your breast reconstruction? Please check one of the following.
- ☐ 5 or less times
 - ☐ 6 to 10 times
 - ☐ More than 10 times
4. Approximately how many times during the PAST SIX MONTHS have you had to visit a doctor because of physical symptoms related to treatment for medical problems **unrelated** to your breast cancer or to your reconstruction? Please check one of the following.
- ☐ 5 or less times
 - ☐ 6 to 10 times
 - ☐ More than 10 times

We would like to learn more about you and your background. Please answer the following questions so that we may better understand your responses.

1. Please check the best description of your current marital situation.
- ☐ Single
 - ☐ Living with a significant other
 - ☐ Married
 - ☐ Widowed
 - ☐ Divorced
 - ☐ Separated
2. We are interested in knowing the degree to which you have participated in regular exercise habits DURING THE PAST SIX MONTHS. The following examples list various exercise activities in terms of their vigorousness and duration.

MILD EXERCISE: leisurely walking, gardening, leisurely biking.

MODERATE EXERCISE: 30 minutes or less of low-impact aerobics, jogging, tennis, biking, swimming, etc.

VIGOROUS EXERCISE: 30 minutes or more of aerobics, running, basketball, stair-stepper, etc.

Please review the following statements and select the one answer which best describes your exercise habits over the past six months.

- ☐ I do not exercise
 - ☐ I do mild exercise 1 to 2 times per week
 - ☐ I do mild exercise 3 or more times per week
 - ☐ I do moderate exercise 1 to 2 times per week
 - ☐ I do moderate exercise 3 or more times per week
 - ☐ I do vigorous exercise 1 to 2 times per week
 - ☐ I do vigorous exercise 3 or more times per week
3. When you did take part in the physical activity or exercise which you checked in Questions 4, for how long did you usually maintain it?
- ☐ 15 minutes or less
 - ☐ Greater than 15 minutes, but less than 45 minutes
 - ☐ 45 minutes or more
 - ☐ I do not exercise
4. Now we are interested in whether or not your exercise routine includes abdominal/stomach and back exercises, such as sit-ups or curl-ups. During the past six months, on average, how many times per week did you specifically exercise your back or stomach muscles?
- ☐ Not at all
 - ☐ Once a week or less
 - ☐ Two to three times per week
 - ☐ More than three times per week

5. Do you currently smoke cigarettes? Yes ____ No ____
6. If you smoke cigarettes, how many packages of cigarettes do you smoke in an average day?
 ____ less than 1/2 pack per day
 ____ 1/2 to 1 pack per day
 ____ more than 1 pack per day
7. Do you currently drink any alcoholic beverages (beer, wine, liquor)? Yes ____ No ____
8. If you currently do drink alcoholic beverages, how many drinks do you consume in an average week (including the weekend)? ____
9. Please check the statement that best describes your current employment situation:
 Read all options carefully before checking just one.
 ____ I am currently employed outside of the home,
 or am seeking employment outside of the home
 ____ I am currently employed outside of the home, on paid or unpaid leave
 ____ I am a homemaker, student, or retired person
 ____ I am disabled due to my breast cancer
 ____ I am disabled but not due to my breast cancer
 ____ Other (please specify): _____
10. If you are currently working outside of the home, how many hours per week do you spend on that work?
 ____ Not currently working outside of the home
 ____ Less than 15 hours per week
 ____ 15 to 40 hours per week
 ____ More than 40 hours per week
11. Which of the following best describes your work history?
 ____ I have not worked in the past three years
 ____ I have worked intermittently for the past three years
 ____ I have been continuously employed for the past three years
12. If you were employed prior to breast reconstruction, what impact has the reconstruction had on your employment?
 ____ It has not been affected
 ____ I had to reduce my hours or type of work
 ____ I have left my job.
13. About what was your total family income from all sources last year before taxes? (Count all income for all household members who live with you. Circle one number for the category that includes your approximate family income last year.)
- (Circle one number)
- | | |
|----------------------|---|
| less than \$15,000 | 1 |
| \$15,000 to \$24,999 | 2 |
| \$25,000 to \$49,999 | 3 |
| \$50,000 to \$75,000 | 4 |
| more than \$75,000 | 5 |
14. How many persons other than yourself are dependent on your family's income? _____

Fact-B (Version 3)**Michigan Breast Reconstruction Outcome Study**
University of Michigan, Ann Arbor

Below is a list of statements that other people with your illness have said are important. By circling one number per line, please indicate how true each statement has been for you during the past seven days.

During the past seven days:
Physical Well-Being

	not at all	a little bit	some what	quite a bit	very much
1. I have a lack of energy.	0	1	2	3	4
2. I have nausea.	0	1	2	3	4
3. Because of my physical condition, I have trouble meeting the needs of my family.	0	1	2	3	4
4. I have pain.	0	1	2	3	4
5. I am bothered by side effects of treatment.	0	1	2	3	4
6. I feel sick.	0	1	2	3	4
7. I am forced to spend time in bed.	0	1	2	3	4

8. Looking at the above seven questions, how much would you say your **Physical Well-Being** affects your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
not at all very much

During the past seven days:
Social/Family Well-Being

	not at all	a little bit	some what	quite a bit	very much
9. I feel distant from my friends.	0	1	2	3	4
10. I get emotional support from my family.	0	1	2	3	4
11. I get support from my friends and neighbors.	0	1	2	3	4
12. My family has accepted my illness.	0	1	2	3	4
13. Family communication about my illness is poor.	0	1	2	3	4
14. I feel close to my partner (or the person who is my main support).	0	1	2	3	4

15. Have you been sexually active during the past year?

No

Yes If yes: I am satisfied with my sex life.

0 1 2 3 4

16. Looking at the above seven questions, how much would you say your **Social/Family Well-Being** affects your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
not at all very much

During the past seven days:
Relationship With The Doctor

	not at all	a little bit	some what	quite a bit	very much
17. I have confidence in my doctor(s).	0	1	2	3	4
18. My doctor is available to answer my questions.	0	1	2	3	4

19. Looking at the above two questions, how much would you say your **Relationship With The Doctor** affects your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
 not at all very much

During the past seven days:
Emotional Well-Being

	not at all	a little bit	some what	quite a bit	very much
20. I feel sad.	0	1	2	3	4
21. I am proud of how I'm coping with my illness.	0	1	2	3	4
22. I am losing hope in the fight against my illness.	0	1	2	3	4
23. I feel nervous.	0	1	2	3	4
24. I worry about dying.	0	1	2	3	4
25. I worry that my condition will get worse.	0	1	2	3	4

26. Looking at the above six questions, how much would you say your **Emotional Well-Being** affects your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
 not at all very much

During the past seven days:
Functional Well-Being

	not at all	a little bit	some what	quite a bit	very much
27. I am able to work (include the work in home).	0	1	2	3	4
28. My work (include work in home) is fulfilling.	0	1	2	3	4
29. I am able to enjoy life.	0	1	2	3	4
30. I have accepted my illness.	0	1	2	3	4
31. I am sleeping well.	0	1	2	3	4
32. I am enjoying the things I usually do for fun.	0	1	2	3	4
33. I am content with the quality of my life right now.	0	1	2	3	4

34. Looking at the above seven questions, how much would you say your **Functional Well-Being** affects your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
 not at all very much

During the past seven days:

Additional Concerns

	not at all	a little bit	some what	quite a bit	very much
35. I have been short of breath.	0	1	2	3	4
36. I am self-conscious about the way I dress.	0	1	2	3	4
37. My arms are swollen or tender.	0	1	2	3	4
38. I feel sexually attractive.	0	1	2	3	4
39. I have been bothered by hair loss.	0	1	2	3	4
40. I worry about the risk of cancer in other family members.	0	1	2	3	4
41. I worry about the effect of stress on my illness.	0	1	2	3	4
42. I am bothered by a change in weight.	0	1	2	3	4
43. I am able to feel like a woman.	0	1	2	3	4

44. Looking at the above nine questions, how much would you say these **Additional Concerns** affect your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
not at all very much

INSTRUCTIONS:

Below is a list of problems people sometimes have. Please read each one carefully, and circle the number to the right that best describes **HOW MUCH THAT PROBLEM HAS DISTRESSED OR BOTHERED YOU DURING THE PAST SEVEN DAYS, INCLUDING TODAY.** Circle only one number for each problem, and do not skip any items. If you change your mind, erase your first mark carefully.

HOW MUCH WERE YOU DISTRESSED BY:		Not At All	A Little Bit	Moderately	Quite A Bit	Extremely
1. Nervousness or shakiness inside	1	0	1	2	3	4
2. Faintness or dizziness	2	0	1	2	3	4
3. The idea that someone else can control your thoughts	3	0	1	2	3	4
4. Feeling others are to blame for most of your troubles	4	0	1	2	3	4
5. Trouble remembering things	5	0	1	2	3	4
6. Feeling easily annoyed or irritated	6	0	1	2	3	4
7. Pains in heart or chest	7	0	1	2	3	4
8. Feeling afraid in open spaces	8	0	1	2	3	4
9. Thoughts of ending your life	9	0	1	2	3	4
10. Feeling that most people cannot be trusted	10	0	1	2	3	4
11. Poor appetite	11	0	1	2	3	4
12. Suddenly scared for no reason	12	0	1	2	3	4
13. Temper outbursts that you could not control	13	0	1	2	3	4
14. Feeling lonely even when you are with people	14	0	1	2	3	4
15. Feeling blocked in getting things done	15	0	1	2	3	4
16. Feeling lonely	16	0	1	2	3	4
17. Feeling blue	17	0	1	2	3	4
18. Feeling no interest in things	18	0	1	2	3	4
19. Feeling fearful	19	0	1	2	3	4
20. Your feelings being easily hurt	20	0	1	2	3	4
21. Feeling that people are unfriendly or dislike you	21	0	1	2	3	4
22. Feeling inferior to others	22	0	1	2	3	4
23. Nausea or upset stomach	23	0	1	2	3	4
24. Feeling that you are watched or talked about by others	24	0	1	2	3	4
25. Trouble falling asleep	25	0	1	2	3	4
26. Having to check and double check what you do	26	0	1	2	3	4
27. Difficulty making decisions	27	0	1	2	3	4
28. Feeling afraid to travel on buses, subways or trains	28	0	1	2	3	4
29. Trouble catching your breath	29	0	1	2	3	4
30. Hot or cold spells	30	0	1	2	3	4
31. Having to avoid certain things, places or activities because they frighten you	31	0	1	2	3	4
32. Your mind going blank	32	0	1	2	3	4
33. Numbness or tingling in parts of your body	33	0	1	2	3	4
34. The idea that you should be punished for your sins	34	0	1	2	3	4
35. Feeling hopeless about the future	35	0	1	2	3	4

HOW MUCH WERE YOU DISTRESSED BY:

Not At All
A Little Bit
Moderately
Quite A Bit
Extremely

36. Trouble concentrating	36	0	1	2	3	4
37. Feeling weak in parts of your body	37	0	1	2	3	4
38. Feeling tense or keyed up	38	0	1	2	3	4
39. Thoughts of death or dying	39	0	1	2	3	4
40. Having urges to beat, injure or harm someone	40	0	1	2	3	4
41. Having urges to break or smash things	41	0	1	2	3	4
42. Feeling very self-conscious with others	42	0	1	2	3	4
43. Feeling uneasy in crowds	43	0	1	2	3	4
44. Never feeling close to another person	44	0	1	2	3	4
45. Spells of terror or panic	45	0	1	2	3	4
46. Getting into frequent arguments	46	0	1	2	3	4
47. Feeling nervous when you are left alone	47	0	1	2	3	4
48. Others not giving you proper credit for your achievements	48	0	1	2	3	4
49. Feeling so restless you couldn't sit still	49	0	1	2	3	4
50. Feelings of worthlessness	50	0	1	2	3	4
51. Feeling that people will take advantage of you if you let them	51	0	1	2	3	4
52. Feelings of guilt	52	0	1	2	3	4
53. The idea that something is wrong with your mind	53	0	1	2	3	4

Pre-Surgery Evaluation
Michigan Breast Reconstruction Outcome Study
University of Michigan, Ann Arbor

(For office use only)
REGISTRATION # _____

I. Personal Information

Today's Date: _____

Your Name: _____

Date of Birth: _____ SS#: _____

Address: _____

City, State, Zip: _____

Telephone: (home) _____ - _____ - _____ (work) _____ - _____ - _____

Contact person or relative who does not live with you:

Name _____

Telephone: (home) _____ - _____ - _____

With regards to your mastectomy:

Date of Mastectomy _____ General Surgeon's name _____

Hospital Name _____ City, State _____

Decision to Seek Surgery

We are interested in why you have chosen to seek breast reconstruction. The following statements reflect some of the reasons why women seek breast reconstruction following a mastectomy. For each statement, please circle the one answer that best describes how true each statement is for you.

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
1. I want to feel whole again.	1	2	3	4	5
2. I want to feel the way I did before my cancer.	1	2	3	4	5
3. I want to wear the same type of clothing I was able to before my breast cancer.	1	2	3	4	5
4. I want to feel attractive.	1	2	3	4	5
5. I want to avoid the need to wear a prosthesis.	1	2	3	4	5
6. I want to have breast reconstruction so that I am not constantly reminded that I had cancer.	1	2	3	4	5
7. I am having surgery mainly because my significant other wants me to.	1	2	3	4	5
8. I want to be more attractive to my significant other.	1	2	3	4	5
9. I want to feel less self-conscious during sexual activity.	1	2	3	4	5
10. I want to improve my relationship with my significant other.	1	2	3	4	5
11. I think that breast reconstruction will enhance my emotional health and self-worth.	1	2	3	4	5

General Health Survey

1. In general, would you say your health is: (Circle One Number)

Excellent	1
Very Good	2
Good	3
Fair	4
Poor	5

2. Compared to one year ago, how would you rate your health in general now? (Circle One Number)

Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

- In one year from now, how do you think your health will be? (Circle One Number)

Much better than today	1
Somewhat better than today	2
About the same as today	3
Somewhat worse than today	4
Much worse than today	5

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(Circle One Number on Each Line)	Yes Limited a Lot	Yes Limited a Little	Not Limited at All
3. Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing several flights of stairs	1	2	3
7. Climbing one flight of stairs	1	2	3
8. Bending, kneeling or stooping	1	2	3
9. Walking more than one mile	1	2	3
10. Walking several blocks	1	2	3
11. Walking one block	1	2	3
12. Bathing or dressing yourself	1	2	3
13. Bending over to brush your teeth	1	2	3
14. Sitting up in bed when you awake in the morning	1	2	3
15. Doing the dishes	1	2	3
16. Arising from a chair	1	2	3
17. Grasping for something, like reaching for a glass from the cupboard	1	2	3

During the **past four weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?**

- | (Circle One Number on Each Line) | Yes | No |
|---|-----|----|
| 18. Cut down the amount of time you spent on work or other activities | 1 | 2 |
| 19. Accomplished less than you would like | 1 | 2 |
| 20. Were limited in the kind of work or other activities | 1 | 2 |
| 21. Had difficulty performing the work or other activities (for example, it took extra effort) | 1 | 2 |

During the **past four weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

- | (Circle One Number on Each Line) | Yes | No |
|--|-----|----|
| 22. Cut down the amount of time you spent on work or other activities | 1 | 2 |
| 23. Accomplished less than you would like | 1 | 2 |
| 24. Didn't do work or other activities as carefully as usual | 1 | 2 |

25. During the **past four weeks**, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups?

- (Circle One Number)
- | | |
|-------------|---|
| Not at all | 1 |
| Slightly | 2 |
| Moderately | 3 |
| Quite a bit | 4 |
| Extremely | 5 |

26. How much **bodily** pain have you had during the **past four weeks**?

- (Circle One Number)
- | | |
|-------------|---|
| None | 1 |
| Very mild | 2 |
| Mild | 3 |
| Moderate | 4 |
| Severe | 5 |
| Very severe | 6 |

27. During the **past four weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework?)

- (Circle One Number)
- | | |
|--------------|---|
| Not at all | 1 |
| A little bit | 2 |
| Moderately | 3 |
| Quite a bit | 4 |
| Extremely | 5 |

For each of the following statements, please circle the one answer that best describes how true each statement is for you.

(Circle One Number on Each Line)

	Definitely True 1	Mostly True 2	Not Sure 3	Mostly False 4	Definitely False 5
28. My breasts are without pain.					
29. My abdomen is sore and painful.	1	2	3	4	5
30. I am frequently troubled by headaches.	1	2	3	4	5
31. My abdomen feels tight.	1	2	3	4	5
32. I have back pain.	1	2	3	4	5

These questions are about how you feel and how things have been with you **during the past four weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past four weeks** . . .

(Circle One Number on Each Line)	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
33. Did you feel full of pep?	1	2	3	4	5	6
34. Have you been a very nervous person?	1	2	3	4	5	6
35. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
36. Have you felt calm and peaceful?	1	2	3	4	5	6
37. Did you have a lot of energy?	1	2	3	4	5	6
38. Have you felt downhearted and blue?	1	2	3	4	5	6
39. Did you feel worn out?	1	2	3	4	5	6
40. Have you been a happy person?	1	2	3	4	5	6
41. Did you feel tired?	1	2	3	4	5	6

42. During the **past four weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

(Circle One Number)

All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

How TRUE or FALSE is each of the following statements for you?

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
43. I seem to get sick a little easier than other people.	1	2	3	4	5
44. I am as healthy as anybody I know.	1	2	3	4	5
45. I expect my health to get worse.	1	2	3	4	5
46. My health is excellent.	1	2	3	4	5

Personal Beliefs

The following items describe feelings that one may have about their appearance and attractiveness. Please circle the number that best describes how true each statement is for you.

(Circle One Number on Each Line)	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
47. I believe that physical attractiveness is important in day-to-day social interaction.	1	2	3	4	5
48. I believe that physical attractiveness is important in acquiring a mate (e.g., spouse, significant other).	1	2	3	4	5
49. I believe that physical attractiveness is important in attracting a sexual partner.	1	2	3	4	5
50. My breasts have always been an important part of my sexuality.	1	2	3	4	5
51. Physical and sexual attractiveness have always been very important to me.	1	2	3	4	5

The following items relate specifically to your feelings about the appearance of your breasts. Please circle the answer that best describes the way you now feel.

(Circle One Number on Each Line)

	Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
1. I feel whole.	1	2	3	4	5
2. I like the way my blouses/sweaters fit.	1	2	3	4	5
3. I like the way I look in a bathing suit.	1	2	3	4	5
4. My bra fits comfortably.	1	2	3	4	5
5. I feel attractive.	1	2	3	4	5
6. I think of my cancer when I look at my breasts.	1	2	3	4	5
7. I like the appearance of my breasts.	1	2	3	4	5
8. My significant other likes the appearance of my breasts.	1	2	3	4	5
9. I feel self-conscious during sexual activity because of the appearance of my breasts.	1	2	3	4	5

Health Complaints

1. The following items describe bodily symptoms that most of us have experienced at one time or another. Please circle the number that corresponds best with the way you have felt during the PAST WEEK. Please answer all questions. Do not think too long before answering.

	Not at all	A little/ slightly	A great deal/ quite a bit	Extremely could not have been worse
Heart rate increase	1	2	3	4
Feeling hot all over	1	2	3	4
Sweating all over	1	2	3	4
Sweating in a particular part of the body	1	2	3	4
Pulse in neck	1	2	3	4
Pounding in head	1	2	3	4
Dizziness	1	2	3	4
Blurring of vision	1	2	3	4
Feeling faint	1	2	3	4
Everything appearing unreal	1	2	3	4
Nausea	1	2	3	4
Butterflies in stomach	1	2	3	4
Pain or ache in stomach	1	2	3	4
Stomach churning	1	2	3	4
Desire to pass water	1	2	3	4
Mouth becoming dry	1	2	3	4
Difficulty swallowing	1	2	3	4
Muscles in neck aching	1	2	3	4
Legs feeling weak	1	2	3	4
Muscles twitching or jumping	1	2	3	4
Tense feeling across forehead	1	2	3	4
Tense feeling in jaw muscles	1	2	3	4

2. Here is a list of health problems that usually last for some time. Do you have any of the following problems? (Check all that apply)

Yes	No	
___	___	Asthma
___	___	Chronic bronchitis or emphysema
___	___	Arthritis or rheumatism
___	___	High blood pressure
___	___	Angina
___	___	Congestive heart failure
___	___	History of stroke
___	___	Cancer (other than breast or skin cancer: specify type _____)
___	___	Diabetes
___	___	Chronic back trouble
___	___	Lupus
___	___	Scleroderma
___	___	Other _____

We would like to learn more about you and your background. Please answer the following questions so that we may better understand your responses.

1. Do you consider yourself primarily:
___ African-American
___ Asian or Pacific Islander
___ Hispanic
___ Native American
___ White
___ Other (please specify): _____
2. Highest level of education completed?
___ Less than high school
___ Completed high school
___ Some college
___ Completed college
___ Some graduate work
___ Graduate degree
3. Please check the best description of your current marital situation.
___ Single
___ Living with a significant other
___ Married
___ Widowed
___ Divorced
___ Separated

4. We are interested in knowing the degree to which you have participated in regular exercise habits DURING THE PAST SIX MONTHS. The following examples list various exercise activities in terms of their vigorousness and duration.

MILD EXERCISE: leisurely walking, gardening, leisurely biking.

MODERATE EXERCISE: 30 minutes or less of low-impact aerobics, jogging, tennis, biking, swimming, etc.

VIGOROUS EXERCISE: 30 minutes or more of aerobics, running, basketball, stair-stepper, etc.

Please review the following statements and select the one answer which best describes your exercise habits over the past six months.

- ☐ I do not exercise
- ☐ I do mild exercise 1 to 2 times per week
- ☐ I do mild exercise 3 or more times per week
- ☐ I do moderate exercise 1 to 2 times per week
- ☐ I do moderate exercise 3 or more times per week
- ☐ I do vigorous exercise 1 to 2 times per week
- ☐ I do vigorous exercise 3 or more times per week

- 4a. When did you take part in the physical activity or exercise which you checked in Question 4, for how long did you usually maintain it?

- ☐ 15 minutes or less
- ☐ Greater than 15 minutes, but less than 45 minutes
- ☐ 45 minutes or more
- ☐ I do not exercise

5. Now we are interested in whether or not your exercise routine includes abdominal/stomach and back exercises, such as sit-ups or curl-ups. During the past six months, on average, how many times per week did you specifically exercise your back or stomach muscles?

- ☐ Not at all
- ☐ Once a week or less
- ☐ Two to three times per week
- ☐ More than three times per week

6. Do you currently smoke cigarettes? Yes ☐ No ☐

7. If you smoke cigarettes, how many packages of cigarettes do you smoke in an average day?

- ☐ less than 1/2 pack per day
- ☐ 1/2 to 1 pack per day
- ☐ more than 1 pack per day

8. Do you currently drink any alcoholic beverages (beer, wine, liquor)? Yes ☐ No ☐

9. If you currently do drink alcoholic beverages, how many drinks do you consume in an average week (including the weekend)? _____

10. Please check the statement that best describes your current employment situation:

Read all options carefully before checking just one.

- ☐ I am currently employed outside of the home, or am seeking employment outside of the home
- ☐ I am currently employed outside of the home, on paid or unpaid leave
- ☐ I am a homemaker, student, or retired person
- ☐ I am disabled due to my breast cancer
- ☐ I am disabled but not due to my breast cancer
- ☐ Other (please specify): _____

11. If you are currently working outside of the home, how many hours per week do you spend on that work?

- ☐ Not currently working outside of the home
☐ Less than 15 hours per week
☐ 15 to 40 hours per week
☐ More than 40 hours per week

12. Which of the following best describes your work history?

- ☐ I have not worked in the past three years
☐ I have worked intermittently for the past three years
☐ I have been continuously employed for the past three years

13. What type(s) of medical insurance coverage do you carry?

(Check yes or no for each one.)

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Blue Cross/Blue Shield
<input type="checkbox"/>	<input type="checkbox"/>	Other Private Insurance (e.g. Aetna, Travelers, etc.)
<input type="checkbox"/>	<input type="checkbox"/>	HMO or Managed Care program (which? _____)
<input type="checkbox"/>	<input type="checkbox"/>	Medicare
<input type="checkbox"/>	<input type="checkbox"/>	Medicaid
<input type="checkbox"/>	<input type="checkbox"/>	None
<input type="checkbox"/>	<input type="checkbox"/>	Other (Which? _____)

14. Does the medical insurance which you carry cover breast reconstruction surgery?

Yes _____ No _____ Don't Know _____

15. About what was your total family income from all sources last year before taxes? (Count all income for all household members who live with you. Circle one number for the category that includes your approximate family income last year.)

(Circle one number)

less than \$15,000	1
\$15,000 to \$24,999	2
\$25,000 to \$49,999	3
\$50,000 to \$75,000	4
more than \$75,000	5

16. How many persons other than yourself are dependent on your family's income? _____

Fact-B (Version 3)**Michigan Breast Reconstruction Outcome Study**
University of Michigan, Ann Arbor

Below is a list of statements that other people with your illness have said are important. By circling one number per line, please indicate how true each statement has been for you during the past seven days.

During the past seven days:

Physical Well-Being

	not at all	a little bit	some what	quite a bit	very much
1. I have a lack of energy.	0	1	2	3	4
2. I have nausea.	0	1	2	3	4
3. Because of my physical condition, I have trouble meeting the needs of my family.	0	1	2	3	4
4. I have pain.	0	1	2	3	4
5. I am bothered by side effects of treatment.	0	1	2	3	4
6. I feel sick.	0	1	2	3	4
7. I am forced to spend time in bed.	0	1	2	3	4

8. Looking at the above seven questions, how much would you say your **Physical Well-Being** affects your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
not at all very much

During the past seven days:

Social/Family Well-Being

	not at all	a little bit	some what	quite a bit	very much
9. I feel distant from my friends.	0	1	2	3	4
10. I get emotional support from my family.	0	1	2	3	4
11. I get support from my friends and neighbors.	0	1	2	3	4
12. My family has accepted my illness.	0	1	2	3	4
13. Family communication about my illness is poor.	0	1	2	3	4
14. I feel close to my partner (or the person who is my main support).	0	1	2	3	4

15. Have you been sexually active during the past year?

No

Yes If yes: I am satisfied with my sex life.

0 1 2 3 4

16. Looking at the above seven questions, how much would you say your **Social/Family Well-Being** affects your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
not at all very much

During the past seven days:
Relationship With The Doctor

	not at all	a little bit	some what	quite a bit	very much
17. I have confidence in my doctor(s).	0	1	2	3	4
18. My doctor is available to answer my questions.	0	1	2	3	4

19. Looking at the above two questions, how much would you say your **Relationship With The Doctor** affects your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
not at all very much

During the past seven days:
Emotional Well-Being

	not at all	a little bit	some what	quite a bit	very much
20. I feel sad.	0	1	2	3	4
21. I am proud of how I'm coping with my illness.	0	1	2	3	4
22. I am losing hope in the fight against my illness.	0	1	2	3	4
23. I feel nervous.	0	1	2	3	4
24. I worry about dying.	0	1	2	3	4
25. I worry that my condition will get worse.	0	1	2	3	4

26. Looking at the above six questions, how much would you say your **Emotional Well-Being** affects your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
not at all very much

During the past seven days:
Functional Well-Being

	not at all	a little bit	some what	quite a bit	very much
27. I am able to work (include the work in home).	0	1	2	3	4
28. My work (include work in home) is fulfilling.	0	1	2	3	4
29. I am able to enjoy life.	0	1	2	3	4
30. I have accepted my illness.	0	1	2	3	4
31. I am sleeping well.	0	1	2	3	4
32. I am enjoying the things I usually do for fun.	0	1	2	3	4
33. I am content with the quality of my life right now.	0	1	2	3	4

34. Looking at the above seven questions, how much would you say your **Functional Well-Being** affects your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
not at all very much

During the past seven days:

Additional Concerns

- 35. I have been short of breath.
- 36. I am self-conscious about the way I dress.
- 37. My arms are swollen or tender.
- 38. I feel sexually attractive.
- 39. I have been bothered by hair loss.
- 40. I worry about the risk of cancer in other family members.
- 41. I worry about the effect of stress on my illness.
- 42. I am bothered by a change in weight.
- 43. I am able to feel like a woman.

not at all	a little bit	some what	quite a bit	very much
0	1	2	3	4
0	1	2	3	4
0	1	2	3	4
0	1	2	3	4
0	1	2	3	4
0	1	2	3	4
0	1	2	3	4
0	1	2	3	4
0	1	2	3	4

44. Looking at the above nine questions, how much would you say these **Additional Concerns** affect your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
not at all very much

INSTRUCTIONS:

Below is a list of problems people sometimes have. Please read each one carefully, and circle the number to the right that best describes HOW MUCH THAT PROBLEM HAS DISTRESSED OR BOTHERED YOU DURING THE PAST SEVEN DAYS, INCLUDING TODAY. Circle only one number for each problem, and do not skip any items. If you change your mind, erase your first mark carefully.

HOW MUCH WERE YOU DISTRESSED BY:		Not At All	A Little Bit	Moderately	Quite A Bit	Extremely
1. Nervousness or shakiness inside	1	0	1	2	3	4
2. Faintness or dizziness	2	0	1	2	3	4
3. The idea that someone else can control your thoughts	3	0	1	2	3	4
4. Feeling others are to blame for most of your troubles	4	0	1	2	3	4
5. Trouble remembering things	5	0	1	2	3	4
6. Feeling easily annoyed or irritated	6	0	1	2	3	4
7. Pains in heart or chest	7	0	1	2	3	4
8. Feeling afraid in open spaces	8	0	1	2	3	4
9. Thoughts of ending your life	9	0	1	2	3	4
10. Feeling that most people cannot be trusted	10	0	1	2	3	4
11. Poor appetite	11	0	1	2	3	4
12. Suddenly scared for no reason	12	0	1	2	3	4
13. Temper outbursts that you could not control	13	0	1	2	3	4
14. Feeling lonely even when you are with people	14	0	1	2	3	4
15. Feeling blocked in getting things done	15	0	1	2	3	4
16. Feeling lonely	16	0	1	2	3	4
17. Feeling blue	17	0	1	2	3	4
18. Feeling no interest in things	18	0	1	2	3	4
19. Feeling fearful	19	0	1	2	3	4
20. Your feelings being easily hurt	20	0	1	2	3	4
21. Feeling that people are unfriendly or dislike you	21	0	1	2	3	4
22. Feeling inferior to others	22	0	1	2	3	4
23. Nausea or upset stomach	23	0	1	2	3	4
24. Feeling that you are watched or talked about by others	24	0	1	2	3	4
25. Trouble falling asleep	25	0	1	2	3	4
26. Having to check and double check what you do	26	0	1	2	3	4
27. Difficulty making decisions	27	0	1	2	3	4
28. Feeling afraid to travel on buses, subways or trains	28	0	1	2	3	4
29. Trouble catching your breath	29	0	1	2	3	4
30. Hot or cold spells	30	0	1	2	3	4
31. Having to avoid certain things, places or activities because they frighten you	31	0	1	2	3	4
32. Your mind going blank	32	0	1	2	3	4
33. Numbness or tingling in parts of your body	33	0	1	2	3	4
34. The idea that you should be punished for your sins	34	0	1	2	3	4
35. Feeling hopeless about the future	35	0	1	2	3	4

HOW MUCH WERE YOU DISTRESSED BY:

Not At All
A Little Bit
Moderately
Quite A Bit
Extremely

36. Trouble concentrating	36	0	1	2	3	4
37. Feeling weak in parts of your body	37	0	1	2	3	4
38. Feeling tense or keyed up	38	0	1	2	3	4
39. Thoughts of death or dying	39	0	1	2	3	4
40. Having urges to beat, injure or harm someone	40	0	1	2	3	4
41. Having urges to break or smash things	41	0	1	2	3	4
42. Feeling very self-conscious with others	42	0	1	2	3	4
43. Feeling uneasy in crowds	43	0	1	2	3	4
44. Never feeling close to another person	44	0	1	2	3	4
45. Spells of terror or panic	45	0	1	2	3	4
46. Getting into frequent arguments	46	0	1	2	3	4
47. Feeling nervous when you are left alone	47	0	1	2	3	4
48. Others not giving you proper credit for your achievements	48	0	1	2	3	4
49. Feeling so restless you couldn't sit still	49	0	1	2	3	4
50. Feelings of worthlessness	50	0	1	2	3	4
51. Feeling that people will take advantage of you if you let them	51	0	1	2	3	4
52. Feelings of guilt	52	0	1	2	3	4
53. The idea that something is wrong with your mind	53	0	1	2	3	4



Michigan Breast Reconstruction Outcome Study, DAMD17-94-J-4044,

ATTACHMENT B
HOSPITAL CHART REVIEW FORM

Reviewer, _____

Date of Review: _____

Please complete each section thoroughly. If any errors are found in the pre-printed patient information, please make corrections in red pen.

Name: _____

Study ID: **1002**

Status: **A**

Hospital Number: _____

DOB: _____

SS number: _____

Home phone: _____

Work phone: 0 - 0

Tissue Diagnosis

- ☐ Infiltrating ductal carcinoma
- ☐ Ductal carcinoma in situ
- ☐ Infiltrating lobular carcinoma
- ☐ Lobular carcinoma in situ
- ☐ Inflammatory carcinoma
- ☐ Cystosarcoma phylloides
- ☐ Family hx of breast CA
- ☐ Other (Specify): _____

L Date of Dx R Date of Dx

- | | | | |
|--------------------------|-------|--------------------------|-------|
| <input type="checkbox"/> | _____ | <input type="checkbox"/> | _____ |
| <input type="checkbox"/> | _____ | <input type="checkbox"/> | _____ |
| <input type="checkbox"/> | _____ | <input type="checkbox"/> | _____ |
| <input type="checkbox"/> | _____ | <input type="checkbox"/> | _____ |
| <input type="checkbox"/> | _____ | <input type="checkbox"/> | _____ |
| <input type="checkbox"/> | _____ | <input type="checkbox"/> | _____ |
| <input type="checkbox"/> | _____ | <input type="checkbox"/> | _____ |
| <input type="checkbox"/> | _____ | <input type="checkbox"/> | _____ |

Cancer Treatment

1. Operation -- Left

Left date ____/____/____

- ☐ Lumpectomy
- ☐ Subcutaneous mastectomy
- ☐ Simple mastectomy
- ☐ Modified radical mastectomy
- ☐ Radical mastectomy

Operation -- Right

Right date ____/____/____

- ☐ Lumpectomy
- ☐ Subcutaneous mastectomy
- ☐ Simple mastectomy
- ☐ Modified radical mastectomy
- ☐ Radical mastectomy

2. Radiation Therapy? ☐ YES ☐ NO (Please Check)

Side: ☐ LEFT ☐ RIGHT (Please Check) (If both, please check both "left" and "right")

Left date: From ____/____/____ to ____/____/____

Right date: From ____/____/____ to ____/____/____

3. Adjuvant Chemotherapy? ☐ YES ☐ NO (Please Check)

Dates: From ____/____/____ to ____/____/____

Reconstruction

Immediate/Delayed

Date: / / ☐ ☐

Right Date: 09/30/94 ☐ ☐

Date: / / ☐ ☐

Hospital: **Univ of MI**

Surgeon: **Wilkins**

NOTES FROM THE MBROS OFFICE

Reviewer Signature _____ Date: _____

Type of Reconstruction:L R

- ☐ ☐ Implant
☐ ☐ Expander/Implant
☐ ☐ Pedicle TRAM
☐ ☐ Free TRAM
☐ ☐ Lat Dorsi
☐ ☐ Reduction
☐ ☐ Other (Specify): _____

Additional Reconstructive ProceduresDates:L R

- ☐ ☐ Implant Exchange
☐ ☐ Capsulectomy/Capsulotomy
☐ ☐ Nipple-Areolar Reconstruction
☐ ☐ Revision/Debulking TRAM Flap
☐ ☐ Scar Revision
☐ ☐ Contralateral Reduction Mammoplasty
☐ ☐ Contralateral Mastopexy
☐ ☐ Contralateral Augmentation
☐ ☐ Other (Specify): _____

Complications of Reconstruction:Category I: Expander/Implant Complications Date of Dx

Type	Left	Right	Treatment
Abscess			
Cellulitis			
Capsular Contracture (Baker III or IV)			
Expander/Implant Deflation			
Hematoma			
Hypertrophic Scar/Keloid			
Overlying Skin Necrosis			
Seroma			
Wound Dehiscence/Implant Exposure			
Other (Specify):			

Category II: TRAM ComplicationsDate of Dx

Type	Left	Right	Treatment
Abdominal Hernia/Laxity Req. Repair			
Abscess			
Cellulitis			
Donor Site Necrosis			
Fat Necrosis (>6 mos Postop)			
Hematoma			
Hypertrophic Scar/Keloid			
Mastectomy Skin Flap Necrosis			
Post-op Anastomotic Thrombosis			
Partial Acute Flap Loss			
Total Flap Loss			
Wound Dehiscence			
Other (Specify):			

Complications of Reconstruction, Con't.:

Category III:Lat Dorsi Complications

Type	Date of Dx		Treatment
	Left	Right	
Abscess			
Cellulitis			
Capsular Contracture (Baker III or IV)			
Implant Deflation			
Hematoma			
Hypertrophic Scar/Keloid			
Flap Skin Necrosis			
Seroma			
Wound Dehiscence/Implant Exposure			
Other (Specify):			

ATTACHMENT C
COMPLICATION CHECK LIST FORM

Mich. Breast Reconstruction Outcome Study-Complications Check List

Name:

DOB:

SS number:

Hm Ph:

Wk Ph:

Study ID: 1034

Surgeon: **Beil**

Instructions: Please keep with chart, notate date and check complications as they occur.

Complications of Reconstruction:**Category I: Expander/Implant Complications**

Type	L	R	Date	Treatment
Abscess				
Cellulitis				
Capsular Contracture (Baker III or IV)				
Expander/Implant Deflation				
Hematoma				
Hypertrophic Scar/Keloid				
Overlying Skin Necrosis				
Seroma				
Wound Dehiscence/Implant Exposure				
Other (Specify):				

Category II: TRAM Complications

Type	L	R	Date	Treatment
Abdominal Hernia/Laxity Req Repair				
Abscess				
Cellulitis				
Donor Site Necrosis				
Fat Necrosis (>6 mos Postop)				
Hematoma				
Hypertrophic Scar/Keloid				
Mastectomy Skin Flap Necrosis				
Post-op Anastomotic Thrombosis				
Partial Acute Flap Loss				
Total Flap Loss				
Wound Dehiscence				
Other (Specify):				

Category III: Lat Dorsi Complications

Type	L	R	Date	Treatment
Abscess				
Cellulitis				
Capsular Contracture (Baker III or IV)				
Implant Rupture/Deflation				
Hematoma				
Hypertrophic Scar/Keloid				
Flap Necrosis				
Seroma				
Wound Dehiscence/Implant Exposure				
Other (Specify):				